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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/092,769	03/07/2002	M. Javad Khosravi	28758.65	9645

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HAYNES AND BOONE, LLP  
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DALLAS, TX 75202

EXAMINER

FETTEROLF, BRANDON J

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 07/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/092,769	KHOSRAVI ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Brandon J. Fetterolf, PhD	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 16 May 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 17-25,28,31-39 and 41-55 is/are pending in the application.
- 4a) Of the above claim(s) 17-24,31-39 and 41-55 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 25 and 28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17 2(a))

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Khosravi et al.

***Response to the Amendment***

The Amendment filed on 05/16/2005 in response to the previous Non-Final Office Action (01/13/2005) is acknowledged and has been entered.

Claims 17-25, 28, 31-39 and 41-55 are currently pending.

Claims 17-24, 31-39 and 41-55 are withdrawn from consideration as being drawn to non-elected inventions.

Claims 25 and 28 are currently pending.

The Terminal Disclaimer filed on May 16, 2005 has been accepted.

**The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.**

**Rejections Maintained:**

Claims 25 and 28 **remain** rejected under 35 U.S.C. 102(e) as being anticipated by Pollak *et al.* (U.S. 6,645,770, 1998) for the reasons of record in the prior Office Action (01/13/2005, pages 6-7) and for the reasons set forth below.

In reference to the previous action which held that Pollack *et al.* disclose (column 1, lines 25-32) methods of assessing the risk of developing prostate cancer and/or differentiating prostate cancer from other prostatic diseases, such as benign prostatic hyperplasia, by measuring IGF-I and/or insulin-like growth factor binding protein-3 (IGFBP-3) and/or PSA levels in a specimen, and calculating a ratio wherein the ratio provides a means for assessing the risk of prostate cancer or differentiating prostate cancer from other prostatic diseases, Applicant's assert (Pages 10-13) that the teachings of Pollak are to use IGF-I, IGFBP-3 and PSA measurements in subjects without any evidence of prostate disease, to predict the risk of prostate cancer occurrence in the future. For example, Applicants submit that the subjects of Pollak had no history of cancer, and the teachings suggests that the measurements of IGF-1 levels in addition to PSA may be better to predict

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subsequent prostate cancer than PSA measurements alone. In contrast, Applicants argue that the present claims describe methods to discriminate between benign prostate disorders and prostate cancer in an individual already having such a disorder or cancer, by calculating an indicator ratio based on at least two of the measured concentrations of either IGF-I, IGFBP-3, and PSA in a sample from that individual. Applicants further assert that none of the teachings of Pollak demonstrate any utility of the methods described to diagnose existing prostate cancer or a benign prostate disease, or to discriminate between existing prostate cancer and a benign prostate disorder. For example, Applicants point to Pollak (column 12, lines 6-20) which indicates that in one particular study IGF-I levels were only of "borderline significance" in predicting prostate cancer risk in men already diagnosed with prostate cancer, and that the retrospective design used in the study could not rule out an effect of the cancer, or treatment, on IGF-I levels. Moreover, Applicants argue that in order for an invention to be anticipated by a prior art discloser under section 102, the reference must contain an "enabling disclosure" (MPEP 2121.01), wherein the disclosure is enabling if the public was in possession of the claimed invention before the date of invention, "possession" being effected if one of ordinary skill in the art could have combined the reference's description of the invention with his/her own knowledge to make the claimed invention. Therefore, Applicants contend that because of Pollak's disclosure of methods to predict the risk of future prostate cancer and statement that "no one has heretofore shown that markers relating to IGF-axis components can also be used as a risk marker for prostate cancer (column 2, line 67 to column 3, lines 1-3), Pollak does not provide an enabling disclosure that anticipates the presently claimed invention. These argument have been carefully considered, but are not found persuasive.

First, the Examiner agrees with Applicants position that Pollak does not specifically provide examples of measuring IGF-I, IGFBP-3 and PSA levels from individuals with existing cancer. However, the argument that the instantly claimed method differs from that of Pollak because the method involves individuals already having a disorder such as cancer is not pertinent since it does not appear that this limitation is suggested in the instantly filed claims. The previous rejection was based on the technical reasoning that necessarily flowed from the teachings of the prior art- the active steps of measuring an insulin-like growth factor binding protein 3 (IGFBP-3) concentration, an insulin-like growth factor (IGF-I) concentration, measuring prostate specific antigen (PSA) concentration; and calculating a ratio based upon at least two of the measured concentration which

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can be used in predicting prostate cancer and/or differentiating cancer from other prostatic diseases, such as benign prostate hyperplasia. As pointed out by Applicants (Remarks, Page 12, last paragraph), Pollak clearly establishes a nexus between prostate cancer and high levels of IGF-I with high PSA levels. As to the question of operability/enableness, the burden is on the applicant to provide facts, such as declaration or affidavits, rebutting the presumption of operability by a preponderance of the evidence, *see In re Sasse*, 629 F.2d 675, 207 USPQ 107 (CCPA 1980). Thus, any argument regarding the enablement of the Pollak patent are moot since Applicant's have not provided any facts rebutting the presumption of operability. For these reasons, Claims 25 and 28 remain rejected under 35 U.S.C. 102(e) as being anticipated by Pollak *et al.* (U.S. 6,645,770, 1998).

Therefore, NO claim is allowed

**All other rejections and/or objections are withdrawn in view of applicant's amendments and arguments there to.**

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brandon J. Fetterolf, PhD whose telephone number is (571)-272-2919. The examiner can normally be reached on Monday through Friday from 8:30 to 5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeff Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Brandon J Fetterolf, PhD  
Examiner  
Art Unit 1642

BF



**GARY B. NICKOL, PH.D**  
**PRIMARY EXAMINER**